K110948

8. 510 (k) Summary

MAY 1 3 2011

1. Submitter Information

Company name	TaiDoc Technology Corporation
Contact person	Teling Hsu
Address	6F, No. 127, Wugong 2nd Rd. Wugu Township, Taipei County 24888, Taiwan
Phone	(+886-2) 6625-8188 ext.1176
FAX	(+886-2) 6625-0288
E-mail	teling.hsu@taidoc.com.tw
Date Prepared	March 30th, 2011

2. Name of Device

Trade Names	Health Care System Software
Product code	NBW; DXN; FLL
Classification Names and Regulations	a) Calculator/data processing module for clinical use, Class I, 21 CFR 862.2100 b) Glucose Test System, Class II, 21 CFR 862.1345 c) Noninvasive Blood Pressure Measurement System, Class II, 21 CFR 870.1130, d) General Hospital, Class II, 21 CFR 880.2910

3. Predicate Device

Trade/Proprietary Name:	Clever Chek Health Care System Software
Common/Usual Name:	Data management software
Submitter	TaiDoc Technology Corporation
510 (k) Number	K070941

4. Device Description

The Health Care System Software is an optional software accessory for use with the following models with data management capabilities: a) blood glucose meters, b) blood glucose plus blood pressure monitors, and c) blood pressure monitors. When use with one of these devices, Health Care System Software transfers data from the device's memory into a computer for enhanced data management.

5. Intended Use

The Health Care System Software is an optional software accessory for use with the following models with data management capabilities: a) Clever Chek blood glucose meters, b) Clever Chek blood glucose plus blood pressure monitors, and c) Clever blood pressure monitors. When use with one of these meters, Health Care System Software transfers data from the device's memory into a computer for enhanced data management.

The Health Care System Software is intended for use in home and clinical settings as an aid for users and their health care professionals to review, analyze and evaluate the historical test results to support health management effectively.

6. Comparison to Predicate Device

The Health Care System Software is substantially equivalent to the Clever Chek Health Care System Software (K070941). Both management software programs can be described as follows:

- have the same intended use and intended users
- have the same data presentation
- have same programming language
- data transferred from the device cannot be changed or modified in any way.

The modifications include:
-Added temperature data tabular display setting
-Added temperature graph display setting
-Added temperature data printer setting

7. Performance Studies

Testing of Health Care System Software included validation of hardware (data transfer through the cable) and software validation. Results demonstrate that the system meets its intended use.

8. Conclusion

Health Care System Software is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 13 2011

Mr. Teling Hsu
Regulatory Affairs Specialist
TaiDoc Technology Corporation
6F, No, 127, Wugong 2nd Road
Wugu Township Taipei County
Taiwan 24888

Re: K110948
Trade/Device Name: Health Care System Software
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: II
Product Code: NBW, DXN, FLL
Dated: May, 4, 2011
Received: May 6, 2011

Dear Mr. Hsu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

7.

Indications for Use

510(k) Number: k110948

Device Name: Health Care System Software

Indications for Use:

The Health Care System Software is an optional software accessory for use with the following models with data management capabilities: a) Clever Chek blood glucose meters, b) Clever Chek blood glucose plus blood pressure monitors, and c) Clever blood pressure monitors. When use with one of these meters, Health Care System Software transfers data from the device's memory into a computer for enhanced data management.

The Health Care System Software is intended for use in home and clinical settings as an aid for users and their health care professionals to review, analyze and evaluate the historical test results to support health management effectively.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use __X__ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K110948

Page 1 of ___1__